

DEC 7 2005

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Abbreviated 510(k): Device modification Bipore Accuflex™ Percutaneous Sheath  
Introducer

510(k) Summary K051513

**Submitted by:**

Keith Paluch  
Consultant  
Bipore, Inc.  
31 Industrial Parkway  
Northvale, NJ 07647

**Date Prepared:**

May 29, 2005 and October 26, 2005

**Proposed Device:**

Bipore Accuflex™ Percutaneous Sheath Introducer

**Product Classification:**

Class II C.F.R. 870.1340 Product code: DYB, Catheter Introducer

**FDA registration number:**

2248069

**Predicate Device:**

510(k) Name

K964814 Bipore Accuflex™ Percutaneous Sheath Introducer

**Indications for Use:**

The Bipore AccuFlex™ Percutaneous Sheath Introducer is recommended for percutaneous introduction of various devices into arteries and/or veins for diagnostic and therapeutic procedures.

Bipore Inc  
Abbreviated 510(k) submission  
Device modification k964814  
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Revised 10/27/05

ATTACH 7



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

DEC 7 2005

Bipore, Inc.  
c/o Mr. Keith Paluch  
31 Industrial Parkway  
Northvale, NJ 07647

Re: K051513  
Bipore Accuflex Percutaneous Sheath Introducer  
Regulation Number: 21 CFR 870.1340  
Regulation Name: Catheter Introducer  
Regulatory Class: Class II (Two)  
Product Code: DYB  
Dated: October 28, 2005  
Received: November 10, 2005

Dear Mr. Paluch:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

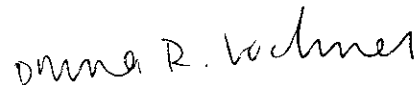
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

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Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Bram D. Zuckerman, M.D.

Director

Division of Cardiovascular Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

### Indications for Use

510(k) Number (if known): K051513

Device Name: Bipore AccuFlex™ Percutaneous Sheath Introducer

Indications for Use: The Bipore AccuFlex™ Percutaneous Sheath Introducer is recommended for percutaneous introduction of various devices into arteries and/or veins for diagnostic and therapeutic procedures.

Prescription Use X  
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF  
NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

*Diana R. Vachner*  
(Division Sign-Off)  
Division of Cardiovascular Devices

510(k) Number K051513